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G5G G4 G5A

(56) Documents Cited

WO 94/25948 A

US 4974461 A

US 5061187 A

US 5055051 A

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UK CL (Edition P) G5G G4 G5A

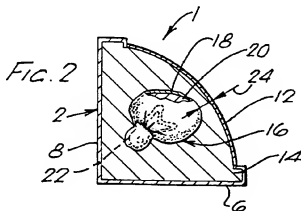
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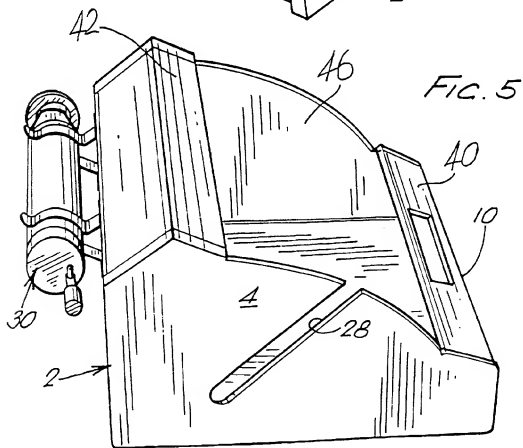
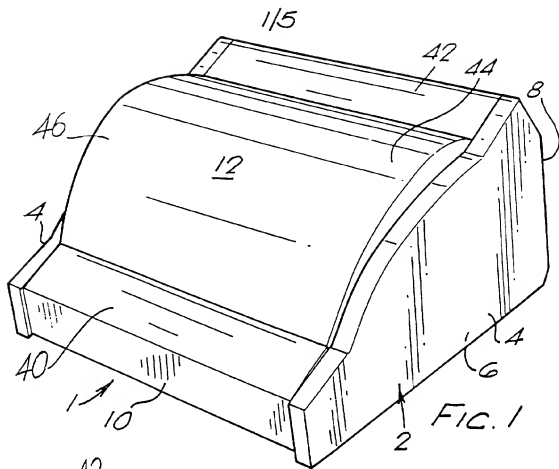
(54) Abstract Title

Simulator For Body Organs

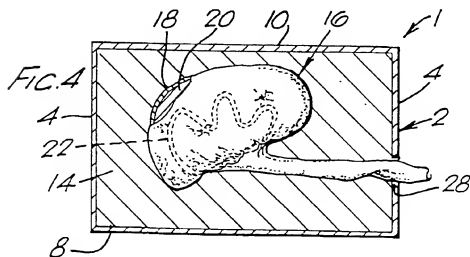
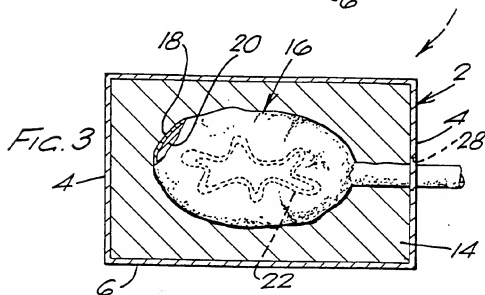
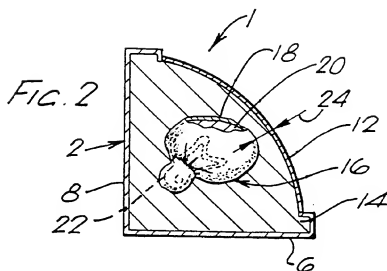
(57) A simulator for medical training comprises replica body organs and surrounding soft tissue made of materials which have similar radiographic densities and acoustic properties to the real subjects, thus providing suitable responses to x-rays and ultrasound. For example, a latex or rubber material provides a skin surface 12 with a suitable consistency for needle entry, soft tissue 14 is formed from stabilised gelatine or a silicon gel, and an organ such as a simulated renal system 16 has an outer surface 18 and internal tubes 22 of silicone rubber or latex together with tissue 20, again formed of silicon gel or modified stabilised gelatine. Other simulated organs are exemplified and the housing for the simulator may carry a syringe 30, Fig 5 (not shown), for injecting coloured fluids for fluoroscopic investigation.

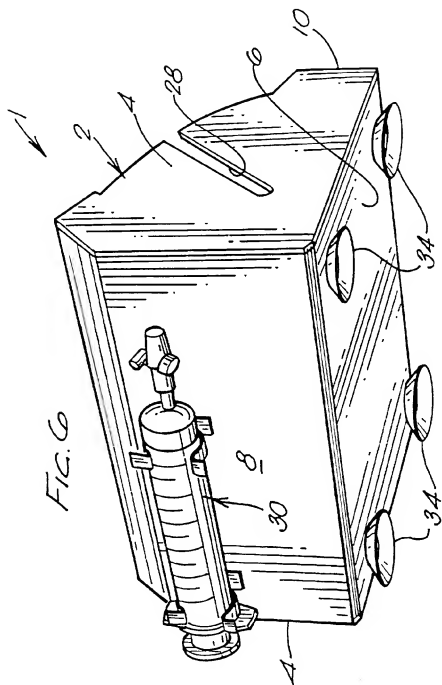


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FIG. 7

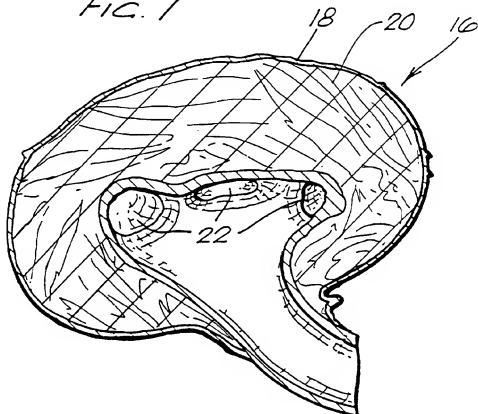
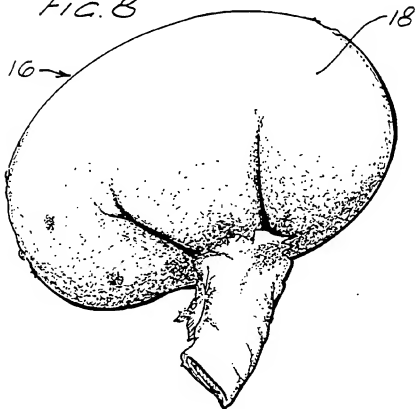
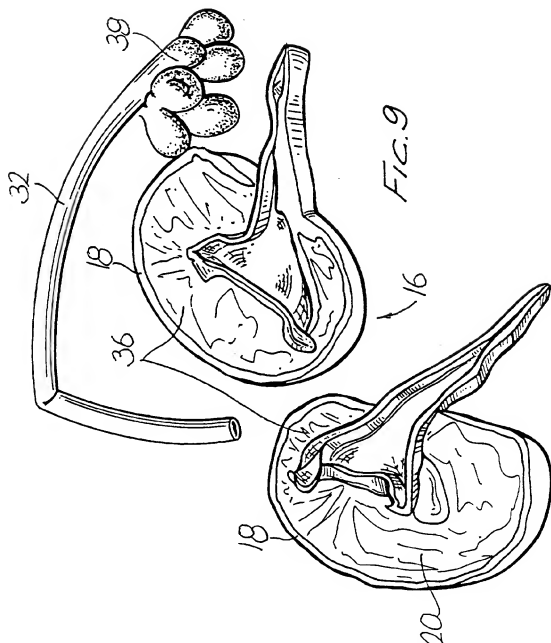


FIG. 8





SIMULATOR

This invention relates to a simulator. The invention is particularly described in the form of a simulator of a patient's renal system for development of percutaneous renal access techniques. The simulator can equally be used for simulating different organs of a patient.

Percutaneous renal access techniques for drainage, antegrade stent insertions and stone extractions are now well established. These techniques are usually ultrasonically or fluoroscopically guided. Training for these radiological/surgical procedures has traditionally taken the form of an apprenticeship.

With increasing public expectation and demand for better training before embarking on minimally invasive procedures, models have been developed in other areas of minimal access surgery and for laparoscopic techniques.

At the present time there are no available models for teaching percutaneous renal techniques and these are traditionally taught while carrying out procedures on patients. Different trainees show a wide range of abilities to pick up manual techniques requiring a degree of dexterity and there is often a shortage of simple cases which are suitable for teaching.

It is an object of the present invention to provide a synthetic model closely simulating the anatomy of a patient which is suitable for both ultrasonically as well as fluoroscopically guided procedures. Reference is particularly, but not exclusively, made to the provision of a synthetic model closely simulating the collecting system, the surrounding renal parenchyma and extrarenal tissues.

According to the present invention there is provided a simulator

Preferably, the components of the simulator are formed of addition cure
10 silicones.

Preferably, an outer surface of the simulator is provided of a latex or rubber material to replicate a patient's skin.

25 Most preferably, the tissue of the organ and the surrounding tissue are formed of RTV 4055 with addition of silicone oil 200% or an equivalent material. Most preferably, the outer surface of the simulated organ and the skin surface are formed of RTV 4055 or an equivalent material. Most preferably, the internal

30 structure of the simulated organ is formed of RTV 1556 or an equivalent material.

Preferably, the components of the simulator are bonded together in an airtight bond. Preferably, the components are bonded together with a silicon gel using a primer.

5 Preferably, a housing is provided for housing the components of the simulator in an arrangement to simulate a segment of a patient's back. The simulated organ may be disposed within the housing in an orientation corresponding to the orientation of the organ in relation to the back of a patient.

10 Preferably, the components comprise a renal parenchyma and a renal collecting system. Preferably, the collecting system includes a simulated ureter.

 Preferably, there is provided a fluid insertion means for inserting fluid into the collecting system via the ureter. Preferably, the fluid insertion means is
15 a syringe.

An embodiment of a simulator in accordance with the present invention will now be described with reference to the accompanying drawings, in which:

20 Figure 1 is a perspective view from above of the simulator;

 Figure 2 is a stylised cross-sectional view from one side of the simulator;

25 Figure 3 is a stylised cross-sectional view from the front of the simulator;

 Figure 4 is a stylised cross-sectional view from above of the simulator;

30 Figure 5 is a perspective view from above of the housing of the simulator;

Figure 6 is a perspective view of the housing of the simulator from below;

5 Figure 7 is a cross-section of a component of a simulated organ of the simulator;

Figure 8 is a side view of a simulated organ of the simulator; and

10 Figure 9 is a perspective view of two halves of an outer component of a simulated organ and an internal component of the simulated organ of the simulator.

Referring to the drawings, a simulator (1) is provided simulating a portion of a patient's back and the patient's renal system including the collecting
15 system, surrounding renal parenchyma and extrarenal tissue. The simulator (1) also simulates the skin of the patient's back.

The simulator (1) according to the present invention can be used to simulate the renal system as described and also other organs such as the
20 ureter, bladder or prostate gland. Other areas or organs of a patient's body can also be simulated such as the ovaries, uterus, heart and blood vessels.

The simulator (1) is formed in a housing (2) of plastics material. The housing (2) has a rectangular base (6) from which extend vertically a back panel
25 (8), a front panel (10) and side panels (4) from the base (6). The back panel (8) is of greater height than the front panel (10). The top surface (44) of simulator (1) has extensions (40, 42) from the front and back panels (10, 8) which together with the tops of the side panels (4) define an opening (46). A simulated portion of a patient's back curves outwardly from the opening (46) in
30 the top surface (44) of the housing (2).

The base (6) has four feet (34) for stabilising the housing (2) on a

supporting surface.

One of the side panels (4) has a slot (28) extending at an angle downwardly from the top edge of the side panel (4).

5

The housing (2) contains a material simulating soft surrounding extrarenal tissue (14) of a patient. The material is a silicon gel or other material which is suitable for use with ultrasound and x-rays, for example KITECKO or stabilised gelatine. In this example RTV 4055 is used with added silicone oil at 200%. The simulated surrounding tissue (14) should have a slightly soft consistency to simulate perirenal fat.

A simulated skin surface (12) encloses the surrounding tissue (14) within the housing (2). The simulated skin surface (12) is formed of silicon rubber which offers similar resistance to needle entry as provided by a patient's skin. The material of the simulated skin surface (12) must also correspond to a patient's skin when ultrasound or x-rays are applied. In this example, the simulated skin surface (12) is formed of RTV 4055.

Disposed within the simulated surrounding tissue (14) is a simulated renal system (16) formed of the components of a simulated renal parenchyma (36) enclosing a collecting system (38) including a simulated ureter (32).

The simulated renal parenchyma (36) has an outer surface (18) and internal tubes (22) formed of a latex material or silicone rubber material. In this example RTV 4055 is used. The internal material (20) of the simulated renal parenchyma (36) is formed of a silicon gel or stabilised modified gelatine or an equivalent material which is suitable for ultrasound and x-ray exposure, for example KITECKO. In this example, the internal material (20) is formed of RTV 4055 with added silicone oil at 200%.

The simulated collecting system (38) is formed of a thin latex material.

In this example RTV 1556 is used. The material is fashioned over a mould to simulate the anatomical configuration of a real renal collecting system with three groups of calyces (upper, middle and lower) in anterior and posterior orientation.

- 5 The simulated collecting system (38) includes a tube (32) representing a patient's ureter for draining in the renal pelvis. Thin latex has the necessary elasticity for filling and distension of the simulated collecting system (38) with contrast or fluid.

- 10 The components simulating the renal system (16), namely the collecting system (38), the renal parenchyma (36) and its surrounding outer surface (18), the surrounding soft extrarenal tissue (14) and the skin surface (12) are bonded together with silicon gel with a primer ensuring that no air bubbles are present between the components which would invalidate ultrasound readings. The materials used must be mutually compatible.

- 15 Synthetic kidney stones can be included in the simulator (1) during manufacture.

- 20 A syringe (30) is provided for attachment to the tube (32) simulating the ureter of a patient. Coloured fluids can be inserted by the syringe (30) into the simulated collecting system (38) to highlight the simulated collecting system (38) by x-ray. The tube (32) simulating the ureter extends from the housing (2) through the slot (28).

- 25 The simulator (1) provides a model simulating the kidney and collecting system embedded in surrounding soft tissue and covered by skin to give a realistic alternative to practice the technique of percutaneous access to the renal tract. During percutaneous access to the renal tract, the patient's kidney and collecting system are completely obscured by the overlying skin and soft tissues. Therefore, the procedures are carried out under fluoroscopic or
30 ultrasonic guidance. The simulator (1) has been formed of materials which have similar radiographic density to the tissues of a patient as well as acoustic

properties similar to a patient's tissues. In addition, the procedures involve inserting needles and tissue dilators and the materials of the simulator (1) must have a similar consistency and must offer similar resistance to a patient's tissues.

5

The simulated collecting system (38) is formed using a mould initially of plasticine or a similar material followed by a harder mould of epoxy resin. The simulated collecting system (38) is then formed from latex using glove manufacturing technology.

10

Modifications and improvements can be made to the foregoing without departing from the scope of the present invention.

CLAIMS

1. A simulator comprising the components of a simulated organ surrounded by material replicating soft tissue of a patient, the components being
5 formed of materials suitable for use with ultrasound and x-rays.
2. A simulator as claimed in claim 1, wherein the simulated organ is a renal system.
- 10 3. A simulator as claimed in claim 1, wherein the simulated organ is any one or more of a kidney, ureter, bladder, prostate gland, ovary, uterus, heart and/or blood vessels.
4. A simulator as claimed in any of claims 1 to 3, wherein the components
15 of the simulator are formed of addition cure silicones.
5. A simulator as claimed in any of claims 1 to 4, wherein the tissue of the simulated organ and the surrounding material replicating soft tissue of a patient are formed of a silicon gel material.
20
6. A simulator as claimed in any of the preceding claim, wherein an outer surface of the simulated organ and an internal structure of the organ are formed of a latex or rubber material.
- 25 7. A simulator as claimed in any of the preceding claims, wherein an outer surface of the simulator is provided of a latex or rubber material to replicate a patient's skin.
8. A simulator as claimed in any of the preceding claims, wherein the
30 materials used to simulate the components of the organ, the surrounding tissue and the skin replicate the consistency of the natural components.

9. A simulator as claimed in any of the preceding claims, wherein the materials used to simulate the components of the organ, the surrounding tissue and the skin respond to the application of ultrasound and x-rays in a similar manner to the natural components.

5

10. A simulator as claimed in any of the preceding claims, wherein the tissue of the organ and the surrounding tissue are formed of RTV 4055 with addition of silicone oil 200% or an equivalent material.

10

11. A simulator as claimed in any of the preceding claims, wherein the outer surface of the simulated organ and the skin surface are formed of RTV 4055 or an equivalent material.

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12. A simulator as claimed in any of the preceding claims, wherein the internal structure of the simulated organ is formed of RTV 1556 or an equivalent material.

20

13. A simulator as claimed in any of the preceding claims, wherein the components of the simulator are bonded together in an airtight bond.

14. A simulator as claimed in claim 12, wherein the components are bonded together with a silicon gel using a primer.

25

15. A simulator as claimed in any of the preceding claims, wherein a housing is provided for housing the components of the simulator in an arrangement to simulate a segment of a patient's back.

30

16. A simulator as claimed in any of the preceding claims, wherein the simulated organ is disposed within the housing in an orientation corresponding to the orientation of the organ in relation to the back of a patient.

17. A simulator as claimed in any of the preceding claims, wherein the

components comprise a renal parenchyma and a renal collecting system.

18. A simulator as claimed in claim 17, wherein the collecting system includes a simulated ureter.

5

19. A simulator as claimed in any of the preceding claims, wherein there is provided a fluid insertion means for inserting fluid simulated organ.

20. A simulator as claimed in claim 19, wherein the fluid insertion means
10 inserts fluid into the collecting system via the ureter.

21. A simulator as claimed in claim 19 or claim 20, wherein the fluid insertion means is a syringe.

15 22. A simulator substantially as hereinbefore described with reference to the accompanying drawings.



Application No: GB 9818909.5
Claims searched: at least claim 1

Examiner: Roland Whaite
Date of search: 1 December 1998

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK CI (Ed.P): G5G (G4, G5A)

Int CI (Ed.6): G09B 23/28 23/30

Other: Online: WPI

Documents considered to be relevant:

Category	Identity of document and relevant passage	Relevant to claims
X	US 5061187 JERATH (see especially column 6, lines 34 to 58 and Table 1)	1,3,6,7,16
X	US 5055051 DUNCAN/DORNIER MEDICAL (whole document and especially column 8, lines 31-34)	1,3,9
X	US 4974461 SMITH et al/US DEPT Of HEALTH (see column 4 line 59 to column 5 line 16)	1,3
X	WO 94/25948 A LIMBS & THINGS Ltd (whole document and especially page 4 lines 13 to 22 and page 8 lines 1 to 10)	1,7,8

X Document indicating lack of novelty or inventive step
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